

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
WESTERN DIVISION

UNITED STATES OF AMERICA, et al.)
Ex rel. BROOKS WALLACE, ROBERT)
FARLEY, and MANUEL FUENTES)

CIVIL ACTION NUMBER
7:18-CV-01010-LSC

Plaintiffs,)

OPPOSED

v.)

ORAL ARGUMENT REQUESTED

EXACTECH INC.,)

Defendant.)

_____)

MEMORANDUM OF LAW IN SUPPORT OF EXACTECH, INC.'S
MOTION TO DISMISS AND FOR JUDGMENT ON THE PLEADINGS

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Pursuant to Federal Rule of Civil Procedure 12(c), Defendant Exactech, Inc. (“Exactech”) respectfully moves this Court for judgment on the pleadings and to dismiss Relators’ Amended Complaint.

INTRODUCTION

False Claims Act (“FCA”) *qui tam* suits fundamentally violate Article II of the Constitution. Article II vests the executive power—including the power to litigate in the Government’s name—in the President alone. “[O]nly . . . persons who are ‘Officers of the United States,’” and over whom the President has significant control, may exercise the power to “conduct[] civil litigation in the courts of the United States for vindicating public rights.” *Buckley v. Valeo*, 424 U.S. 1, 140 (1976) (per curiam); see *Morrison v. Olson*, 487 U.S. 654, 696 (1988). Yet the FCA allows private citizens to take responsibility for litigating on the Government’s behalf.

The conflict between the FCA’s grant of authority to relators and the requirements of Article II of the Constitution has been noted for decades. See *Riley v. St. Luke’s Episcopal Hosp.*, 252 F.3d 749, 768 (5th Cir. 2001) (Smith, J., dissenting). Just two months ago, three Supreme Court Justices acknowledged the “substantial arguments” that “Congress cannot authorize a private relator to wield executive authority to represent the United States’ interests in civil litigation.” *U.S. ex rel. Polansky v. Exec. Health Res., Inc.*, 143 S. Ct. 1720, 1741 (2023) (Thomas,

J. dissenting) (citing Judge Smith’s dissent in *Riley*); *see id.* at 1737 (Kavanaugh, J., and Barrett, J., concurring) (agreeing with Justice Thomas on this point).

Justice Kavanaugh, joined by Justice Barrett, wrote that the Supreme Court “should consider the competing arguments on the Article II issue in an appropriate case.” *Id.* at 1737. This is that case. The Government has declined to intervene, yet Relators continue to prosecute this action in the Government’s name—and in so doing have made significant and consequential policy decisions on the Government’s behalf. This violates Article II of the Constitution, which requires individuals who take “primary responsibility” for litigation on behalf of the Government to be appointed in accordance with the Appointments Clause. U.S. Const., art. II, § 2, cl. 2; *Buckley*, 424 U.S. at 140. *Qui tam* relators are not appointed at all, much less in accordance with the Appointments Clause.

It also violates the Take Care Clause, which requires the President to “take Care that the Laws be faithfully executed.” U.S. Const., art. II, § 3; *see Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 484 (2010). Given the broad authority granted to Relators under the FCA and the limited ability of the President to exercise control over Relators, the Take Care Clause’s requirements have not been met. *See Morrison*, 487 U.S. at 695-696.

Because Relators’ continued prosecution of this action violates Article II, moreover, Relators lack standing under Article III to litigate before this Court. Relators do not allege any individual injuries. Relators’ Article III standing must rest, if at all, on an assignment from the Government. Because the Government may not assign its authority to Relators under Article II, however, there is no valid assignment, and Relators thus lack Article III standing.

This Court should grant judgment on the pleadings to Exactech. Appointments Clause challenges are part of a special class of structural constitutional objections that must be considered regardless of whether they were raised initially. In the alternative, the Court should dismiss this action for lack of subject matter jurisdiction.

BACKGROUND

A. Legal Background.

The FCA, 31 U.S.C. § 3729 *et seq.*, is “unusual” among federal statutes because its *qui tam* provisions “authoriz[e] private parties—known as relators—to sue on the Government’s behalf.” *Polansky*, 143 S. Ct. at 1726.

The FCA grants a relator a panoply of rights. To start, it allows the relator to “bring a civil action” in the “name of the Government.” 31 U.S.C. § 3730(b)(1). From that point on, the relator may remain a party even if the Government intervenes

to take “primary responsibility” over the action during the 60-day seal period. *Id.* § 3730(b)(2), (c)(1).

If the Government initially declines to intervene, however, the “lead role” in the case “falls to the relator” as “the only person then pressing the suit.” *Polansky*, 143 S. Ct. at 1726. The Government retains only a limited interest, with a right to stay certain discovery, 31 U.S.C. § 3730(c)(4), and a right to a portion of the recovery, *id.* § 3730(d)(2). As an interested party, the Government may intervene later to move to dismiss under Rule 41(a), or for other reasons. *See Polansky*, 143 S. Ct. at 1730. But to do so, the Government must make “a showing of good cause,” and nothing it does may limit “the status and rights” of the relator. 31 U.S.C. § 3730(c)(3).

This scheme has “long inhabited something of a constitutional twilight zone.” *Polansky*, 143 S. Ct. at 1741 (Thomas, J. dissenting). Both the federal courts and the United States have recognized the conflict between Article II—which assigns the executive power to the President alone—and the FCA’s delegation of authority to private citizens. *See, e.g., U.S. ex rel. Kelly v. Boeing Co.*, 9 F.3d 743, 757-759 (9th Cir. 1993); Constitutionality of the Qui Tam Provisions of the False Claims Act, 13 Op. O.L.C. 207 (1989). The Eleventh Circuit recently identified these

constitutional questions without resolving them. *Yates v. Pinellas Hematology & Oncology, P.A.*, 21 F.4th 1288, 1312 (11th Cir. 2021).

In a recent opinion, Justice Thomas wrote that “there is good reason to suspect that Article II does not permit private relators to represent the United States’ interests in FCA suits” where the Government does not initially intervene. *Polansky*, 143 S. Ct. at 1742 (Thomas, J. dissenting). Justice Kavanaugh and Justice Barrett agreed that there are “substantial arguments that the *qui tam* device is inconsistent with Article II.” *Id.* at 1737 (Kavanaugh, J., and Barrett, J., concurring).

B. Facts and Procedural History.

Relators brought this *qui tam* suit asserting claims on behalf of the United States and 25 States plus the District of Columbia. ECF No. 1. Relators allege that Exactech submitted false claims to the Medicare and Medicaid programs, Veterans Administration, and various state agencies by selling purportedly defective total knee arthroplasty (“TKA”) implants. *Id.* This Court struck Relator’s original complaint for shotgun pleading, *see* ECF No. 49, and Relators’ state-law claims have been dismissed without prejudice, *see* ECF No. 63.

The Government reviewed the complaint under seal for over a year. Following its review, the United States notified the parties and the Court of its decision not to intervene. *See* ECF No. 18. As a matter of statute, Relators have “the right to conduct the action.” 31 U.S.C. § 3730(b)(4)(B). Although the United

States retains the ability to intervene upon a showing of good cause, *id.* § 3730(c)(3), it has not done so since declining to intervene.

Throughout these proceedings, Relators have exercised control over the case and the claims they are bringing on behalf of the Government. Relators made the initial decision to pursue the case. *See* ECF No. 1. Relators decided to move forward with the litigation despite the Government’s decision not to intervene. *See* ECF No. 18. Relators have engaged in multiple rounds of dispositive briefing. *See* ECF Nos. 37, 44, 58, 61, 143, 150, 161, 162. And Relators also have engaged in extensive settlement negotiations with Exactech, notably without the Government’s involvement. *See* ECF Minute Entries of settlement proceedings before Coogler, J., on Nov. 3, 2022, Nov. 4, 2022, Jan. 19, 2023, May 22, 2023, May 23, 2023, May 24, 2023, and Notice of settlement conference held on July 21, 2023.

During the course of this litigation, Relators’ theory of the case has evolved into a complicated set of novel regulatory propositions. Relators argue that every time Exactech learned that a surgeon performed a revision surgery to replace a Finned Tibial Tray (the tibial-tray component of Exactech’s Optetrak knee prosthesis, hereafter the “Device”) that had prematurely loosened—for whatever reason—Exactech was required to submit an adverse-event report to the FDA. *See* ECF No. 184 at 19. If Exactech did not submit that report on every single occasion,

Relators say that Exactech violated its mandatory reporting obligations and contend that this regulatory violation rendered the Device “misbranded.” *See id.* Despite an absence of legal support for the proposition, Relators assert that a misbranded device is categorically ineligible for Medicare reimbursement. *See, e.g.*, ECF No. 54 ¶¶ 96–101; ECF No. 150 at 22-26, 44, 46-47. The standard for Medicare coverage and reimbursement, though, is that a medical device be “reasonable and necessary” for “the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” 42 U.S.C. § 1395y(a)(1)(A).¹

Although the Medicare coverage standard makes no reference to other regulatory schemes, and although the Device was cleared by FDA for commercial use through the long-established 510(k) process, *see, e.g.*, ECF No. 54 ¶ 28; ECF No. 144 at 6; ECF No. 150 at 17, Relators argue that reimbursement is contingent on unrealistically perfect compliance with all FDA regulations. *See, e.g.*, ECF No. 150 at 44, 57, 59-60. In short, Relators assert that regulatory non-compliance, no matter how “minor or insubstantial,” *Universal Health Services, Inc. v. U.S. ex rel.*

¹ CMS recently promulgated, and then rescinded, a rule further defining the meaning of “reasonable and necessary.” *Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of “Reasonable and Necessary”*, 86 Fed. Reg. 2987, 3009 (Jan. 14, 2021) (promulgated as part of 42 C.F.R. § 405.201(b)); *Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of “Reasonable and Necessary”*, 86 Fed. Reg. 62,944 (Nov. 15, 2021).

Escobar, 579 U.S. 176, 194 (2016), renders a medical device categorically ineligible for reimbursement by Medicare if the device can be deemed misbranded.²

From there, Relators surmise that every claim for payment from Medicare for a Device is a false claim under the FCA because misbranded devices cannot be sold in the United States. *See* ECF No. 184 at 20-21, 28-30. That is, Relators contend that failure to submit even one adverse event report renders a device ineligible for reimbursement as a matter of law, thereby giving rise to potential treble damages and substantial per-claim penalties. Relators take this position even though there is “no statutory condition tying adverse event reporting to eligibility for reimbursement.” *U.S. ex rel. Crocano v. Trividia Health Inc.*, 615 F. Supp. 3d 1296, 1312 (S.D. Fla. 2022). And Relators ignore that their false-certification claim is legally unsupportable: “because compliance with FDA regulations ‘is not required for payment by Medicare and Medicaid, [the manufacturer] has not falsely stated

² A review of FDA guidance makes plain that the misbranding regulations bear little or no relation to how a product actually performs for a medical patient. *See General Controls for Medical Devices*, FDA, <https://www.fda.gov/medical-devices/regulatory-controls/general-controls-medical-devices> (last visited Aug. 15, 2023).

such compliance to the government.” *Id.* (quoting *U.S. ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694, 702 (4th Cir. 2014)).³

Given the novelty and untenability of Relators’ position, it is unsurprising that Relators presented no support from FDA or CMS officials to corroborate their theories.

LEGAL STANDARD

Because this motion “properly challenges subject matter jurisdiction under Rule 12(b)(1),” this Court must “satisfy itself as to the existence of its power to hear the case.” *Morrison v. Amway Corp.*, 323 F.3d 920, 925 (11th Cir. 2003) (internal quotation marks omitted). It is thus “free to independently weigh facts” and matters outside the pleadings, and the burden of proof rests with Relators, as “the party averring jurisdiction.” *Nixon v. Nationwide Mut. Ins. Co.*, No. 7:15-CV-00186-LSC,

³ Relators made an analogous argument based on alleged non-compliance with Current Good Manufacturing Practice regulations, *see, e.g.*, ECF No. 150 at 34-35; ECF No. 54 ¶¶ 85-86, asserting that this alleged non-compliance rendered the Device adulterated, and thereby ineligible for reimbursement. That argument also seeks to transform minor and insubstantial non-compliance with FDA regulations into a basis for another agency, CMS, to automatically deem a device ineligible for coverage and reimbursement, and further seeks to transform the submission of claims for medically necessary procedures into a federal fraud offense. Relators’ claims regarding the Veterans Administration, *see, e.g.*, ECF No. 54 ¶ 158, follow a similar logic.

2015 WL 6735205, at *2 (N.D. Ala. Nov. 4, 2015) (Coogler, J.) (quoting *Amway*, 323 F.3d at 925, and citing *Thomson v. Gaskill*, 315 U.S. 442, 446 (1942)).

Alternatively, judgment on the pleadings is appropriate where “there are no material facts in dispute, and judgment may be rendered by considering the substance of the pleadings and any judicially noticed facts.” *Horsley v. Rivera*, 292 F.3d 695, 700 (11th Cir. 2002); *see* Fed. R. Civ. P. 12(c). The court must dismiss the complaint where the plaintiffs “would not be entitled to relief under any set of facts ... consistent with [their] allegations.” *Horsley*, 292 F.3d at 700.

This motion is timely. A motion under Rule 12(c) is allowed at any time “[a]fter the pleadings are closed” so long as it does not “delay trial.” Fed. R. Civ. P. 12(c). This motion will not delay trial, as there is no current trial date, and the motion presents a purely legal question that does not require discovery—and regardless, no trial should proceed where subject matter jurisdiction remains in question.

Exactech’s Appointments Clause and Take Care Clause challenges implicate this Court’s subject matter jurisdiction and cannot be forfeited. *See* Fed. R. Civ. P. 12(h)(3); *infra* Part I.C. These constitutional arguments are part of a small category of “nonjurisdictional structural constitutional objections” that may be raised at any stage of litigation. *Freytag v. Comm’r*, 501 U.S. 868, 878-879 (1991). Constitutional defenses, moreover, are not subject to forfeiture under Rule 8(c)(1).

See S. Track & Pump, Inc. v. Terex Corp., No. CV 08-543-LPS, 2013 WL 5461615, at *2 (D. Del. Sept. 30, 2013) (finding defendant “has not waived its constitutional challenge” by failing to raise it in a pleading), *rev’d on other grounds*, 618 F. App’x 99 (3d Cir. 2015). In any event, this Circuit applies Rule 8 liberally, allowing defendants to raise “an affirmative defense that [they] did not even plead” in a post-answer motion as long as it does not prejudice the nonmovant. *Jackson v. City of Centreville*, 269 F.R.D. 661, 662 (N.D. Ala. 2010) (Coogler, J.) (quoting *Hassan v. USPS*, 842 F.2d 260, 263 (11th Cir. 1988)). Here, there is no prejudice.

DISCUSSION

I. THE QUI TAM PROVISIONS OF THE FALSE CLAIMS ACT VIOLATE THE APPOINTMENTS CLAUSE.

The FCA’s *qui tam* provisions contravene the Appointments Clause. *See* U.S. Const., art. II, § 2, cl. 2. The Appointments Clause states that “Officers of the United States” must be nominated by the President “with the Advice and Consent of the Senate,” and that “Congress may by Law vest the Appointment of such inferior Officers, as they think proper, in the President alone, in the Courts of Law, or in the Heads of Departments.” *Id.* Importantly, the Supreme Court has held that “*only* ... persons who are ‘Officers of the United States’” appointed in accordance with the Appointments Clause may “discharge[]” the “primary responsibility for conducting civil litigation in the courts of the United States for vindicating public rights.”

Buckley, 424 U.S. at 140 (emphasis added). Relators were not appointed in accordance with the Appointments Clause, and they thus lack authority to continue litigating this action.

A. The FCA’s Grant of Authority to Relators Is Inconsistent with Article II and Separation of Powers.

Buckley’s holding squarely governs this case. Because Relators are not “appointed as an officer of the United States,” *Cochise Consultancy, Inc. v. U.S. ex rel. Hunt*, 139 S. Ct. 1507, 1514 (2019), Congress’s attempt to delegate litigation authority to Relators violates Article II.

The text of the Appointments Clause mandates this result. The phrase “Officers of the United States” was “intended to have substantive meaning,” describing individuals “to whom substantial executive or administrative authority is given by statute.” *Buckley*, 424 U.S. at 124-126. *Buckley* expressly rejected a limited construction of that term which viewed “Officer” status “merely” as a matter of “protocol.” *Id.* at 125. While Congress can create “offices” in a formal sense, its ability to delegate executive *authority* is “inevitably bounded” by the limitations in the Appointments Clause’s “express language.” *Id.* at 138-139. Unless it follows that Clause’s procedures, Congress may delegate to individuals only those functions that Congress can “carry out by itself” or duties “sufficiently removed from . . . enforcement of the public law.” *Id.* at 139. Any attempt to reach beyond those limits

and “ingraft executive duties” on unappointed individuals unconstitutionally “usurp[s] the power of appointment by indirection.” *Springer v. Gov’t of Philippine Islands*, 277 U.S. 189, 202 (1928).

The separation-of-powers principles embedded in the Appointments Clause reinforce these substantive constraints. The “roots” of that Clause are “structural and political” and exist to prevent one branch from “aggrandizing its power at the expense of another.” *Freytag*, 501 U.S. at 878. The Framers “addressed these concerns by carefully husbanding the appointment power to limit its diffusion.” *Id.* at 883. Congressional activity that violates this “principle of limitation” is a grave concern, threatening “the Constitution’s structural integrity” and the interests “of the entire Republic.” *Id.* at 878, 880, 884.

Those principles are at their height where an individual litigates on behalf of the Government. The President has “exclusive authority” to enforce the law “through civil or criminal process” and enjoys “absolute discretion” over when to bring a case. *United States v. Nixon*, 418 U.S. 683, 693 (1974); *Heckler v. Chaney*, 470 U.S. 821, 831-832 (1985). Because a “lawsuit is the ultimate remedy for a breach of the law,” the Constitution entrusts litigation responsibilities to the President alone, “not to the Congress.” *Buckley*, 424 U.S. at 138. In *Buckley*, the Supreme Court accordingly held that Congress violated Article II by delegating civil

litigation authority, including the ability to “institute a civil action” on behalf of the United States, to a commission comprised of eight members, only two of whom were appointed by the President. *Id.* at 111-113. More generally, the Supreme Court has emphasized that under Article II, “[t]here must . . . be an officer or officers” who “determine when the United States shall sue” and “to be responsible” for conducting that litigation. *United States v. San Jacinto Tin Co.*, 125 U.S. 273, 279 (1888).

This FCA *qui tam* suit violates those fundamental requirements, permitting precisely what *Buckley* forbids. The FCA allows Relators to “institute a civil action” in the name of the Government. *See Buckley*, 424 U.S. at 111; 31 U.S.C. § 3730(b)(1). The FCA operates to divest the United States of the “primary responsibility for prosecuting the action” and gives that responsibility to Relators. *See* 31 U.S.C. § 3730(c)(1), (c)(3). Relators have exercised complete control over this case, deciding which claims to prosecute, when to enter settlement negotiations, and the like. There is no question that Relators are suing, purportedly, to vindicate public rights. This FCA suit is “brought in the name of the Government,” the injury Relators “assert is exclusively to the Government,” and any bounty Relators receive is simply a portion of the United States’ alleged damages. *Polansky*, 143 S. Ct. at 1727 (quoting 31 U.S.C. § 3730(b)(1)). Any authority exercised by Relators must

comply with Article II of the Constitution—and those constitutional requirements are plainly not met in this case.

A handful of out-of-circuit courts have reached the opposite conclusion, holding that the Appointments Clause applies only to individuals employed by the Government—not to private citizens, such as relators. *See, e.g., Riley v. St. Luke's Episcopal Hosp.*, 252 F.3d 749, 757-758 (5th Cir. 2001) (en banc); *The Constitutional Separation of Powers Between the President and Congress*, 20 Op. O.L.C. 124 (1996). That precedent is neither persuasive nor binding on this Court and, for two reasons, this Court should not follow it.

First, concluding that the Appointments Clause applies only to individuals employed by the Government—and not to individuals exercising government authority who are *not* employed by the Government—gets the Appointments Clause backwards. *See, e.g., Kelly*, 9 F.3d at 758 n.21; *U.S. ex rel. Taxpayers Against Fraud v. Gen. Elec. Co.*, 41 F.3d 1032, 1041 (6th Cir. 1994). The Appointment Clause, by its very terms, makes clear that *only* Officers of the United States—appointed and confirmed in accordance with the Appointments Clause—may exercise authority reserved for Officers of the United States, regardless of whether they are employed by the Government.

In fact, when Congress designates individuals to lead government litigation, it does so by appointment. The independent counsel statute, for instance, expressly provides for appointment by the Attorney General and the courts, 28 U.S.C. § 592(c), even though the independent counsel is tapped only temporarily for a “single task.” *Morrison*, 487 U.S. at 672; *see also* 5 U.S.C. § 1211(b) (stating that the “Special Counsel shall be appointed by the President, by and with the advice and consent of the Senate”). Caselaw to the contrary lacks examples of Congress delegating similar authority to private citizens.⁴

Second, concluding that the Appointments Clause applies only to individuals employed by the Government undermines basic principles of separation of powers. If the Appointments Clause truly is so limited, “all that Congress or the President must do to circumvent [its] strictures” “is to delegate authority to someone who has not officially been appointed.” *Riley*, 252 F.3d at 768 (Smith, J. dissenting). This cannot be right. The Framers “embedded” “separation-of-powers” concepts in the Appointments Clause specifically to “prevent[] Congress from dispensing power too

⁴ Some cases point to the existence of “private attorneys-general” provisions. *Taxpayers Against Fraud*, 41 F.3d at 1041-42. Semantics aside, those provisions allow a citizen to sue “on his own behalf,” not the Government’s. *E.g.*, 33 U.S.C. § 1365(a) (Clean Water Act); 42 U.S.C. § 3613(a) (Fair Housing Act).

freely.” *Freytag*, 501 U.S. at 878, 880. The Court should not interpret the FCA’s *qui tam* provisions to circumvent the Appointment Clause’s core requirements.

B. The History of *Qui Tam* Litigation Does Not Establish the FCA’s Constitutionality.

Qui tam litigation has a long pedigree, stretching back to the Founding. “Standing alone, however, historical patterns cannot justify contemporary violations of constitutional guarantees,” even if the practice “covers our entire national existence” or even “predates it.” *Polansky*, 143 S. Ct. at 1741 (Thomas J., dissenting) (internal quotation marks omitted) (quoting *Marsh v. Chambers*, 463 U.S. 783, 790 (1983), and *Walz v. Tax Comm’n of City of New York*, 397 U.S. 664, 678 (1970)). The history of *qui tam* litigation falls well short of the “long, unbroken line of common-law precedent” or the “open, widespread, and unchallenged” practice that informs the Constitution’s meaning. *New York State Rifle & Pistol Ass’n, Inc. v. Bruen*, 142 S. Ct. 2111, 2136-37 (2022) (internal quotation marks omitted).

For starters, the FCA differs in key respects from the several *qui tam* statutes passed by the First Congress. Many of the statutes did not expressly permit relators to sue on behalf of the Government; they instead awarded informers a share of any recovery by the Government. *See Vermont Agency of Nat. Res. v. U.S. ex rel. Stevens*, 529 U.S. 765, 777 n.7 (2000) (collecting statutes). Those statutes do not

pose the same Article II concerns. At least one statute, moreover, required a citizen bringing suit to have “suffered a private injury”—meaning that the citizen was not litigating solely on behalf of the Government but was instead seeking to recover for an individual injury. *Id.* at 776 n.5 (citing Act of May 31, 1790, ch. 15, § 2, 1 Stat. 124-125 (allowing author to sue and receive half of civil penalty for violation of their copyright)); *Riley*, 252 F.3d at 773 & n.35 (Smith, J. dissenting). Further, the early *qui tam* statutes have long since been repealed, and do not represent a long and unbroken historical tradition. *See Note, The History and Development of Qui Tam*, 1972 Wash. U. L. Q. 81, 100-101 (1972).

These early statutes—enacted between 1789 and 1794—were adopted when the Executive Branch was in its infancy. At that time, there was no Department of Justice, and the Executive Branch’s “nugatory prosecutorial” force “could not adequately monitor fraud.” *Riley*, 252 F.3d at 774 (Smith, J. dissenting). Congress “largely abandoned the use of *qui tam* statutes in the nineteenth century,” and “all of the *qui tam* provisions enacted by the First Congress have been repealed.” *Id.* The widespread “fraudulent use of federal funds during the Civil War,” *Stevens*, 529 U.S. at 792, later precipitated the adoption of the FCA, Act of Mar. 2, 1863, ch. 67, § 3, 12 Stat. 698. The FCA’s adoption long after the Founding—and in response to the unique exigency created by the Civil War—does not justify the continuing violation

of Article II of the Constitution more than 200 years later. *See Marsh*, 463 U.S. at 791 (contrasting actions “considered carefully” with those “taken thoughtlessly, by force of long tradition”).

Relying on that history also produces bizarre results. Multiple early American and English *qui tam* statutes authorized the prosecution of criminal cases on behalf of the Government. Act of Apr. 30, 1790, ch. 9, §§ 16, 17, 1 Stat. 116 (authorizing informer to prosecute and receive bounty for criminal larceny); 3 William Blackstone, *Commentaries* *160. Yet even courts upholding the FCA’s constitutionality recognize that “criminal prosecution”—a power that “cuts . . . to the heart of the Executive’s constitutional duty”—may not be delegated to private citizens. *Riley*, 252 F.3d at 755. Reliance on history alone does not offer a rational way to limit Congress from “let[ting] loose a posse of *ad hoc* deputies” to prosecute cases in the Government’s stead. *See U.S. ex rel. Milam v. Univ. of Texas M.D. Anderson Cancer Ctr.*, 961 F.2d 46, 49 (4th Cir. 1992).

C. Relators Lack Standing to Sue Under Article III, Requiring Dismissal of This Suit.

Because Relators lack authority to prosecute this action under Article II of the Constitution, they also lack Article III standing—requiring this Court to dismiss the suit. Relators do not allege individual Article III injury. Instead, they assert injury *on behalf of the United States*. *See* ECF No. 54 at 70-76 (alleging “the United

States,” not Relators, “has suffered substantial damages”). The Supreme Court held in *Stevens* that—assuming relators have authority to litigate on behalf of the United States—an alleged injury to the United States suffices to create Article III standing. *Stevens*, 529 U.S. at 773-774, 778 n.8.

In *Stevens*, however, the Supreme Court did not address whether a relator who *lacks* authority under Article II to litigate on behalf of the Government nevertheless has Article III standing. *Stevens* held only that where relators are “partial assignee[s] of the United States,” they may “assert the injury in fact suffered by the assignor.” *Id.* at 773 & n.4 (recognizing the Court has “routinely entertained [assignee’s] suits”). But Relators in this case are *not* “partial assignees” of the United States, because that assignment violates Article II of the Constitution.

An assignee “only has standing if it was *validly* assigned the right to sue.”⁵ *MSPA Claims 1, LLC v. Tenet Fla., Inc.*, 918 F.3d 1312, 1318 (11th Cir. 2019) (emphasis added). Congress cannot “assign” its claims—and the ability to conduct

⁵ The Court in *Stevens* expressly declined to address “whether *qui tam* suits violate Article II.” *Id.* at 778 n.8. It thus “left unaddressed” “the source of Congress’ power to effect partial assignments.” *Polansky*, 143 S. Ct. at 1742 (Thomas, J. dissenting). Although *Stevens* suggested that the Article II question itself was not jurisdictional, the Supreme Court did not examine whether an *invalid* Congressional assignment means that a relator lacks Article III standing. As caselaw on assignment makes clear, if there is “no valid assignment,” an assignee cannot “have derivative standing.” *Texas Life, Accident, Health & Hosp. Serv. Ins. Guar. Ass’n v. Gaylord Ent. Co.*, 105 F.3d 210, 214, 216-217 (5th Cir. 1997).

litigation on its behalf—to private parties without running afoul of Article II. *See supra* pp. 11-19. The FCA’s attempt to assign authority that Congress lacks authority to assign is necessarily invalid. *See Norton v. Shelby County*, 118 U.S. 425, 442 (1886) (“[a]n unconstitutional act is not a law” and “it creates no office”). “Because the underlying assignment of [the United States’] claims was invalid,” Relators thus lack the injury-in-fact necessary for Article III standing. *See US Fax L. Ctr., Inc. v. iHire, Inc.*, 476 F.3d 1112, 1120 (10th Cir. 2007).

This Court accordingly lacks subject matter jurisdiction over this action. The United States has chosen not to intervene, and Relators may not litigate on behalf of the United States. There is no proper plaintiff in this lawsuit with Article III standing, and no Article III injury for this Court to adjudicate. This Court should dismiss Relators’ suit.

II. THE QUI TAM PROVISIONS OF THE FALSE CLAIMS ACT VIOLATE THE TAKE CARE CLAUSE.

The FCA’s delegation of authority to Relators also violates the Constitution’s Take Care Clause. *See* U.S. Const., art. II, § 2, cl. 2; *id.* art II, § 3. Article II vests the “entire ‘executive Power’” in “the President alone” who must “take Care that the Laws be faithfully executed.” *Id.*; *Seila L. LLC v. Consumer Fin. Prot. Bureau*, 140 S. Ct. 2183, 2197 (2020). But the President cannot satisfy the Take Care clause “if he cannot oversee the faithfulness” of his subordinates. *Free Enter. Fund*, 561 U.S.

at 484. Consistent with that constitutional requirement, Congress may not transfer litigating authority from the President to individuals over whom the President does not exercise “sufficient control.” *Morrison*, 487 U.S. at 695-696. Congress breached that limit when it enacted the FCA’s *qui tam* provisions, allowing unaccountable, private citizens to act as de facto prosecutors.

The Take Care Clause’s requirements are stringent. In *Morrison*, the Supreme Court narrowly approved Congress’s decision to vest prosecutorial power in an independent counsel under the Ethics in Government Act of 1978. *See id.* Recognizing that the Act reduced the President’s control over certain prosecutions, the Court found the Act constitutional only as a result of four key limitations on the independent counsel’s authority: (1) the independent counsel could be appointed only at the Attorney General’s request; (2) the independent counsel was required to follow Department of Justice policy; (3) the Attorney General could define the independent counsel’s jurisdiction; and (4) the Attorney General could remove the independent counsel for good cause. *Id.*

The Supreme Court’s decision in *Morrison* was soundly criticized by Justice Scalia, who made clear the dangers of permitting Congress to delegate Executive Power to independent prosecutors without sufficient oversight by the President. *See id.* at 699 (Scalia, J., dissenting) (“Frequently an issue of this sort will come before

the Court clad, so to speak, in sheep’s clothing . . . [b]ut this wolf comes as a wolf.”). Although *Morrison* remains on the books, the Supreme Court has made clear that the statute upheld in *Morrison* represents “the outermost constitutional limits” on Congress’s ability to delegate Executive power. *Seila L.*, 140 S. Ct. at 2199-200 (citing *PHH Corp. v. Consumer Fin. Prot. Bureau*, 881 F.3d 75, 196 (D.C. Cir. 2018) (Kavanaugh, J. dissenting)); *id.* at 2216 (Thomas, J., and Gorsuch, J., concurring in part and dissenting in part) (quoting Justice Scalia’s *Morrison* dissent approvingly).⁶

The FCA’s delegation of executive power to *qui tam* relators goes far beyond the delegation in *Morrison* and is patently unconstitutional. None of the important restrictions on the independent counsel upheld in *Morrison* are present here. And the controls that do exist on *qui tam* relators are insufficient to safeguard the “President’s ability to perform his constitutional duty.” *Seila L.*, 140 S. Ct. at 2235 (Kagan, J., Ginsburg, J., Breyer, J., and Sotomayor, J., concurring in the judgment with respect to severability and dissenting in part) (quoting *Morrison*, 487 U.S. at 691).

First, the FCA is an unprecedented restriction on the President’s removal authority. Article II requires that the President “must have some ‘power of removing

⁶ Exactech preserves the argument that *Morrison* was wrongly decided and that the Supreme Court should adopt Justice Scalia’s dissent in *Morrison*. Even under *Morrison*, however, the FCA’s *qui tam* provisions violate the Take Care Clause.

those for whom he can not continue to be responsible.”’ *Free Enter. Fund*, 561 U.S. at 493 (quoting *Myers v. United States*, 272 U.S. 52, 117 (1926)). But the FCA affords *no* such power: The Attorney General cannot “remove the relator from the litigation under any circumstances.” *Riley*, 252 F.3d at 763 & n.19 (Smith, J. dissenting); *see* 31 U.S.C. § 3730(c)(1), (c)(3).

The FCA’s controls are imperfect substitutes. The United States retains authority to *seek* dismissal under the FCA only *if* it intervenes in the lawsuit. *See* § 3730(c)(3); *Polansky*, 143 S. Ct. at 1730. This limited authority, however, does not remedy the Take Care Clause violation in this case. The President cannot dismiss a *qui tam* lawsuit for any reason at all. Instead, the President must demonstrate the burdens of continued litigation outweigh the benefits. *See* 31 U.S.C. § 3730(c)(2)(A); *Polansky*, 143 S. Ct. at 1734.

That option also is far removed from the President’s traditional removal power. “Good cause” removal began as “an impediment to, not an effective grant of, Presidential control.” *Morrison*, 487 U.S. at 706 (Scalia, J., dissenting). But Congress in the FCA went further and “mandated that the Executive must investigate, intervene, and motion to dismiss” a suit that it does not want to pursue. *Riley*, 252 F.3d at 761 n.13. The ability to voluntarily dismiss “the action” under 31 U.S.C. § 3730(c)(2)(A) also is of limited use. While the President can normally

remove particular attorneys on a case, or instruct them to act differently, dismissal offers only one option: end the case entirely. As the Eleventh Circuit clarified when interpreting Rule 41’s identical language, the power to dismiss the “action” means the dismissal “can only be for an *entire* action, and not an individual claim.” *Rosell v. VMSB, LLC*, 67 F.4th 1141, 1144 (11th Cir. 2023) (emphasis added); *see Polansky*, 143 U.S. at 1733-34 (holding “Rule 41’s standards” apply to voluntary dismissals in FCA cases). Ending the litigation entirely presents a significant downside to dismissal, and it may lead the Government not to intervene where it would otherwise attempt to exercise control. Limiting the removal power in that way flies in the face of the President’s “absolute discretion” over when and how to enforce the law through civil suits. *See Heckler*, 470 U.S. at 831.

Second, the FCA allows relators to exercise the power of prosecutorial discretion. Relators may initiate a prosecution without prior approval from the Department of Justice. *See* 31 U.S.C. § 3730(b)(1). And they are not required to follow Department of Justice policy⁷ or guard the United States’ interests in that

⁷ The Department of Justice Manual provides extensive legal and policy guidelines for FCA actions, including outlining “factors” and “considerations” that “the Department of Justice, in its discretion, takes into account ... when evaluating the appropriate resolution of FCA matters.” U.S. Dep’t of Justice, Justice Manual § 4-4.112 (May 2019), *available at* <https://www.justice.gov/jm/jm-4-4000-commercial-litigation#4-4.112>.

judgment. The FCA also allows relators to decide when a prosecution should end. *See id.* § 3730(c)(3). Indeed, “[o]ne of the greatest *unilateral* powers a President possesses under the Constitution . . . is the power to protect individual liberty by essentially under-enforcing federal statutes regulating private behavior.” *In re Aiken County*, 725 F.3d 255, 264 (D.C. Cir. 2013) (Kavanaugh, J.) (emphasis in original). Yet under the FCA, relators are permitted to exercise such decision-making authority. Congress’s delegation of those responsibilities strikes at the “core of prosecutorial discretion.” *In re Wild*, 994 F.3d 1244, 1260 (11th Cir. 2021) (en banc).

It is up to the relator—and not the Executive Branch—to decide which claims to pursue and how to frame the arguments in support of those claims. If the President believes an FCA lawsuit should proceed but disagrees with the specific claims identified by the relator—or the relator’s legal arguments in support of those claims—the President cannot axe specific claims or arguments. Instead, the President’s only recourse is to seek dismissal of the action, and dismissal is not guaranteed.

Third, relators can create precedent that undermines the United States’ litigating interests. In one recent example, the United States had to settle a *qui tam* action while an appeal was pending to prevent the Eleventh Circuit from potentially

“affirm[ing] the district court’s narrow interpretation of FCA liability, thereby impairing FCA enforcement efforts throughout the circuit.” *United States v. Everglades Coll., Inc.*, 855 F.3d 1279, 1284 (11th Cir. 2017) (explaining that the United States intervened to settle because it “believed an appeal was risky”). Similarly, “a relator may make sweeping allegations that, while true, he is unable effectively to litigate, but which nonetheless bind the government, via res judicata.” *Riley*, 242 F.3d at 763 (Smith, J. dissenting). Normally, the United States carefully considers both the precedential implications of an appeal and the scope of its complaint. The FCA, however, permits relators—who are “motivated primarily by prospects of monetary reward rather than the public good”—to bind the Government in future cases. *Hughes Aircraft Co. v. U.S. ex rel. Schumer*, 520 U.S. 939, 949 (1997). Granting this authority to *qui tam* relators violates the Take Care Clause.

Courts outside the Eleventh Circuit have held that the United States’ “significant control” over *qui tam* relators dispels any Take Care Clause concerns.⁸ *Riley*, 252 F.3d at 753-757; *see also Taxpayers Against Fraud*, 41 F.3d at 1041;

⁸ The FCA’s incompatibility with the Take Care Clause is an open question in the Eleventh Circuit. In *Yates*, the Eleventh Circuit decided that the Eight Amendment’s prohibition on excessive fines applies to monetary awards in FCA *qui tam* suits because the United States retains enough control over the litigation that it effectively “imposes” the award on the defendant. 21 F.4th at 1310, 1312-13. Crucially, *Yates* declined to extend its observations to the Article II context. *Id.* at 1312.

Kelly, 9 F.3d at 749-757; *U.S. ex rel. Stone v. Rockwell Int’l Corp.*, 282 F.3d 787, 805-807 (10th Cir. 2002); *U.S. ex rel. Kreindler & Kreindler v. United Techs. Corp.*, 985 F.2d 1148, 1155 (2d Cir. 1993). These circuits rely on the United States’ initial ability to settle the dispute, as well as its ability to intervene, to hold that the Take Care Clause is satisfied. *See Riley*, 252 F.3d at 753-757; *Taxpayers Against Fraud*, 41 F.3d at 1041; *Kelly*, 9 F.3d at 749-757; *Stone*, 282 F.3d at 805-807; *Kreindler & Kreindler*, 985 F.2d at 1155. These precedents, however, are not binding in the Eleventh Circuit, and they do not take into account Justice Thomas’s persuasive analysis in *Polansky*.

The existence of controls, moreover, does not answer the underlying Article II question—whether the FCA’s restrictions “impede[] the President’s ability to perform his constitutional duty.” *Seila L.*, 140 S. Ct. at 2199 (internal quotation marks omitted). On that score, these controls fall short. They fail to maintain the President’s “exclusive control” over the “quintessentially executive activity” of deciding which cases to prosecute. *See Morrison*, 487 U.S. at 706 (Scalia, J. dissenting). And they go beyond any previously approved restrictions on the President’s removal power. *See Seila L.*, 140 S. Ct. at 2199-200.

Under Article II, the “buck stops with the President.” *Free Enter. Fund*, 561 U.S. at 493. Congress violated that principle when it allowed relators to exercise

Executive power without the accountability required of the President's subordinates. That violation is an independent reason to dismiss Relators' claims and why Relators are not proper plaintiffs under Article III.

CONCLUSION

For the foregoing reasons, the Court should order judgment on the pleadings in favor of Defendant, or in the alternative, dismiss for lack of jurisdiction.

Respectfully submitted this 15th day of August, 2023,

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CERTIFICATE OF SERVICE

I hereby certify that on this 15th day of August, 2023, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notice of such filing to all attorneys of record.

/s/ Harlan I. Prater, IV
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